



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

MAY 25 2000

0089 '00 MAY 30 P1:48

- Joseph Mendelson, III
Legal Director
Center for Food Safety
c/o International Center for Technology
310 D Street, NE
Washington, DC 20002

Docket 99P-0033

Dear Mr. Mendelson:

On May 8, 2000, you wrote the Commissioner, Food and Drug Administration (FDA), expressing concern about the lack of Agency final response to Citizen Petition Docket No. 99P-0033. I am responding to your letter on behalf of the Commissioner.

Citizen Petition (CP) No. 99P-0033, received on January 7, 1999, seeks amendments to remove exclusions, change labeling, and increase the record keeping requirements in 21 CFR 589.2000. (Substances Prohibited from Use in Animal Food or Feed; Animal Proteins Prohibited in Ruminant Feed, finalized at 62 FR 30936 (June 5, 1997). FDA regulations at 21 CFR 10.30(e)(2)(iii) allow the Agency to issue a tentative response to a Citizen Petition. On September 7, 1999, FDA provided a tentative response to CP99-0033 advising you that the requested actions would require additional time for scientific, legal, and policy analysis and consultation. Due to limited technical resources and competing priorities, the Agency has not completed its review of your Citizen Petition. Therefore, FDA is unable to issue a final response at this time.

As a result of concerns expressed in your letter about the appearance of several unusually young Creutzfeldt-Jacob Disease (CJD) cases in the United States, we contacted the Centers for Disease Control and Prevention (CDC). In addition to assuring us that ongoing CJD surveillance continues to show no evidence of nvCJD in the United States, CDC indicated that it was investigating the specific hypothesis that several unusually young CJD cases might represent the emergence of an additional variant of CJD related to Chronic Wasting Disease (CWD) of deer and elk. To date, this investigation has not supported a causal link.

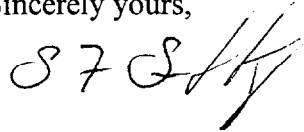
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The FDA has an ongoing effort directed at protecting public health from all transmissible spongiform encephalopathies (TSE). The FDA Interagency TSE Working Group has since its inception, marshaled joint public health protection efforts with international groups and domestic agencies. We will continue this work. However, our resources are limited and we are applying them to matters we believe are of higher priority, at this time. We estimate that it will be several months before a final response can be issued.

Sincerely yours,

A handwritten signature in black ink, appearing to read "S F Sundlof", with a stylized flourish at the end.

Stephen F. Sundlof, D.V.M., Ph.D.
Director, Center for Veterinary Medicine